510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Summary preparation date : April 22, 2002

K 021643

DEC 13 2002

1. GENERAL INFORMATION

Trade Name	HA ORBITAL IMPLANT
Common Name	Orbital Implant
Classification Name	Eye Sphere Implant
Class	II
Product Code	HPZ
CFR section	21 CFR 886.3320
Device panel	Ophthalmology
Submitter's name and address	Laboratoire VILLANOVA VILLANOVA *Chirurgie* STÉPHANE VILLANOVA (Geneal Manager) 30 bis Cours Gambetta F 34000 MONTPELLIER – FRANCE Phone +33 (0)4 67 06 50 51 Fax +33 (0)4 67 58 41 22 e-mail: lab.villanova@wanadoo.fr
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2. PREDICATE DEVICE

Trade Name	Bio-Eye® hydroxyapatite ocular implant Integrated Orbital Implant Inc
510(k)	K 982562
Common Name	Orbital Implant
Classification Name	Eye Sphere Implant
Class	II
Product Code	HPZ
CFR section	21 CFR 886.3320
Device panel	Ophthalmology

3. DEVICE DESCRIPTION

HA ORBITAL IMPLANTS are intra-orbital synthetic hydroxyapatite ($Ca_{10}(Po4)_6(OH)_2$) implants with a minimal 95 % guaranteed purity.

Their porosity is 75% (pore diameter: 200-500 µm). The porosity of the hydroxyapatite facilitates its colonization by fibrovascular tissue, which offers the advantages of reduced risk of infection or implant extrusion.

They are available in the following diameters: 16, 17, 18, 19, 20 and 22 mm.

4 INTENDED USE

HA ORBITAL IMPLANTS are intra-orbital synthetic hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$) implants designed to fill in the orbital cavity following enucleation, evisceration or during secondary implantation.

5 PERFORMANCE DATA

HA ORBITAL IMPLANTS are made of hydroxyapatite which conforms to the ASTM F1185-88 (reapproved 1993) : « Standard specification for composition of ceramic hydroxylapatite for surgical implants ». This FDA recognized consensus standard covers materials characterization and biocompatibility.

The safety and effectiveness of the HA ORBITAL IMPLANTS have been assessed via data reviewed from the literature. Large and numerous studies of hydroxyapatite have been performed and have demonstrated the well tolerance, the improved motility and the low incidence of complications. Most of these studies were performed with the predicate device. The long term benefits as well risks are now well determined.

Hydroxyapatite as an ocular implant appears to offer a significant improvement over all previously used materials made of silicone, PMMA or other synthetic material. Hydroxyapatite orbital implant is associated with few post operative problems consisting mainly in overlying tissue breakdown and exposure. These complications are generally the result of inadequate surgical technique and can be easily managed.

Several studies have demonstrated that synthetic and coralline orbital implants present a similar profile in terms of complications, safety and effectiveness.

6 SUBSTANTIAL EQUIVALENCE

- Both present and predicate devices have the same intended use that is to fill in the orbital cavity following enucleation, evisceration or during secondary implantation.
- Both present and predicate devices are microporous sphere-shaped implants with interconnected pores.
- Both present and predicate devices are manufactured of hydroxyapatite of the same chemical formula : $(Ca_{10}(PO_4)_6(OH)_2)$. The present device is made of surgical grade synthetic hydroxyapatite whereas the predicate device is manufactured of coralline hydroxyapatite.
- Both present and predicate devices are available in several diameters and supplied sterile. The present device is gamma sterilized whereas the predicate device is ethylene oxide sterilized.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2002

Laboratoire Villanova
c/o Isabelle Drubaix
Regulatory Affairs Manager
IDEE Consulting
Residence Blue Marine
65 rue Leon Garet
Le Touquet, France

Re: K021643
Trade/Device Name: HA Orbital Implant
Regulation Number: 21 CFR 886.3320
Regulation Name: Eye Sphere Implant
Regulatory Class: Class II
Product Code: HPZ
Dated: September 6, 2002
Received: October 24, 2002

Dear Dr. Drubaix:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K021643

Device Name : HA ORBITAL IMPLANT

Indications for Use:

HA ORBITAL IMPLANTS are intra-orbital synthetic hydroxyapatite ($Ca_{10}(PO_4)_6(OH)_2$) implants designed to fill in the orbital cavity following enucleation, evisceration or during secondary implantation.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K021643

Prescription Use ✓ or Over-the-Counter Use
(PER 21 CFR 801.109)

(optional Format 1-2-96)